forwarded emails from his supervisor, Mary DePond, about his concerns regarding falsification of authorizations to transfer patients and potentially fake prescriptions to the Sanofi corporate legal department, human resources, Ms. DePond's regional director and a Vice-President. He received no response save for an email sent some months later asking for the key to his locker so that his pharmaceutical samples could be retrieved. He is unaware of any investigative or curing actions undertaken by Sanofi in response to his written concerns.

75. Rather than report such activities to law enforcement or take steps to ensure that no fraud was afoot, Hamilton's supervisors instead only focused on converting these high-volume prescription writers from Ambien to Ambien CR. As discussed below, these same physicians all resisted converting from Ambien to Ambien CR until Ambien CR became listed on the state formularies because until then Medicare reimbursement was difficult to obtain. Despite Hamilton and his team's arranging to falsify Treatment Authorization Requests ("TARS") information for these providers, their conversion rates remained very low initially. Hamilton's supervisors were so concerned about these low conversion rates that a corporate manager – Relator John Doe – was dispatched to meet Hamilton and tour his territory with him.

76. On information and belief, these psychiatrists and pharmacies defrauded Medicare, Medicaid and Medi-Cal of millions of dollars in prescription monies.

E. Sanofi Increased Its Use of Kickbacks to Induce the Switching of Patients from Ambien to Ambien CR

77. In 2005, the expiration of Ambien's patent threatened Sanofi with enormous potential loss of revenue. Ambien CR was supposed to be Sanofi's Life Cycle Management Strategy for Ambien. Sometimes, the executives at Sanofi jokingly referred to the CR in Ambien CR as "Continuous Revenue." To combat the threat of losing Ambien, Sanofi hoped to convert existing Ambien users to Ambien CR which had been approved for sale in 2005 but faced

numerous obstacles, including the fact that many Managed Care companies and physicians hesitated at reimbursing or switching because they believed there was no difference between the two drugs and that Sanofi only created Ambien CR because the patent on Ambien was expiring. Also, there were steps that had to be taken with insurance companies to cover payments for Ambien CR as it initially was not on many insurance company formularies. Sanofi changed its performance evaluation and bonus system from one based on numbers of prescriptions written by a sales representative's doctors to a system that evaluated a representative based on how many patients the representative was able to switch from Ambien to Ambien CR.

78. Sanofi undertook a reckless and massively financed campaign of illegal marketing, including the falsification of insurance paperwork in order to switch Ambien patients to Ambien CR without regard for patient welfare or medical necessity. Illegal kickbacks paid through Lunch/Learn, Speaker Programs and International Conference programs played a central role in these illegal marketing activities.

79. No expense was spared in implementing these corporate plans. The marketing budgets for this period show that in 2005 Sanofi spent a total of $15.6 million for its "access" programs which included Lunch/Learn and $9.2 million on its "Speaker" programs. In 2006, that amount rose by a million to $16.7 with $7 million dollars being spent on "access" and $9.7 million dollars being paid for the Speaker programs. Performance bonuses for sales representatives were tied to their success at "conversion" – that is, switching Ambien patients to Ambien CR. As part of the effort to switch patients from Ambien to Ambien CR, Sanofi directed its sales representatives to begin also offering kickbacks to nurses and pharmacists. Sales representative like Relator Hamilton had never previously spent money on nurses and pharmacists until Sanofi began its efforts to convert patients to Ambien CR. This was because of

the nurses' front-line position with fielding phone calls from pharmacies about whether to switch patients to the more expensive Ambien CR or keep them on generic Ambien.

80. Sanofi's goal of switching 50% of Ambien patients to Ambien CR did not go smoothly at first and sales representatives like Relator Hamilton were instructed to increase their efforts through even greater use of kickbacks. Notable examples of the way Sanofi utilized its "Access" program's funds for kickbacks to doctors in the form of expensive meals for the doctors and/or their staff in an attempt to induce and influence the doctors to switch their patients from Ambien to Ambien CR include:

a. $2,730.00 for a dinner program held at Ruth's Chris Steak House in Woodland Hills, California on April 20, 2006;

b. $4,000.00 requested for a dinner program held at Chapter 8 in Agoura Hills, California on July 12, 2006;

c. $3,228.22 for a nurses' dinner program held at Ruth's Chris Steakhouse in Woodland Hills, California on August 30, 2006;

d. $3,500.00 requested for a dinner program held at Ruth's Chris Steakhouse in Woodland Hills, California on February 8, 2007; and

e. Multiple office lunches for doctors' offices, including lunches nearly every month for the office of Drs. Trabulus, Fishman, Kivowitz, Delafield and Goodman, on multiple occasions, including August 10, 2005, September 20, 2005, November 7, 2005, December 4, 2005, May 22, 2006, July 12, 2006, and October 30, 2006, each ranging from $520-$660 dollars per lunch.

81. Kickbacks to Nurses: Sanofi's upper-level management and corporate officers focused their sales force on nurses as an important target for kickbacks. Nurses were deemed valuable targets for kickbacks because: (1) patients' requests for refills were frequently handled by nurses and/or other medical staff who could be persuaded to switch the patients' prescription at that time to Ambien CR; and, (2) patients might only see a nurse and not a physician during a visit so it was important to induce the conversion process at the nurse level. Sanofi sales representatives were instructed to ask nurses handling refills to switch an Ambien patient asking

for a refill to Ambien CR by authorizing Ambien CR prescriptions without consulting the physician. This tactic by Sanofi specifically sought to induce nurses to violate Cal. Bus. & Prof Code Section 2735.1 and the licensing regulations of other Plaintiff States as well which required nurses in non-clinical settings to seek authorization from a physician before writing or authorizing prescriptions. Sales representatives were required to turn in weekly information on the numbers of refills by individual nurses ("Nursing Trackers"). The goal of the sales representatives was to have the nurses feel obligated to convert patients in return for the regular free meals (such as lunches, desserts, coffees) and other benefits being provided to them. Ideally, some nurses could be persuaded to make the switch without even involving the physician. The sales representatives would then compare the reports from nurses with tracking data on a doctor's conversion rate. If the nurses were found to have misled the sales representative or were underperforming, the sales representative would cease taking them to lunch and/or having lunches brought to the staff.

a. In a November 6, 2006 Sanofi S.A. Field Coaching Report of Relator Hamilton, Mary Depond provides the following feedback: "work with your counterparts to ensure all Nursing and Pharmacy programs/monies are conducted and utilized."

b. In or about January 2007, Sanofi Vice President of Sales Mike Cahill advised field sales force professionals that they should be taking nurses out to lunch so that their practices would switch their Ambien prescriptions to Ambien CR. Vice President Mike Cahill stated to field sales professionals that if they had not taken their nurses out to lunch 9 times each, they were not doing their job; he additionally instructed field sales professionals to spend unlimited money and offer lunches to nurses so they would switch from Ambien to Ambien CR.

c. In an April 2007 Marketing & Strategy Tactics POA (Plan of Action), Defendants listed dinners and lunches among the action items for its Nursing Program to promote Ambien. Specifically, the objective and tactic were identified: to "recruit nurses as advocates for Ambien CR" and "nursing in-service programs using current opportunity funds." The 2007 budget for "opportunity funds" – within an even greater budget for "professional education programs" – was $11.5 million dollars and field sales professionals received $625 - $825 each per month.

d. In a July 7, 2006 Sanofi S.A. Field Coaching Report of Relator Hamilton, Mary Depond instructs: "Utilize additional I:REM $3,000.00 for Pharmacy and Nursing Programs by Sept. 1st."

82. Kickbacks to Pharmacists: Pharmacists were deemed valuable targets for kickbacks because when patients came to pharmacies to fill Ambien CR prescriptions, the pharmacist had the choice of letting the patient know that Ambien CR cost more than Ambien because Ambien CR was not yet on any formulary or the pharmacist could take the extra step of calling the doctors' office to ask for a TAR (treatment authorization request) form or a PA (prior authorization) form which would allow the price of Ambien CR to be fully covered. An additional benefit was that the more Ambien CR prescriptions were filled, the sooner it would be added to the formularies. For example, Relator Hamilton's manager suggested doing lunches in the most important pharmacies during the Ambien CR launch and he received frequent reminders to utilize the monies budgeted for Pharmacy and Nursing programs. As with nurses, Sanofi instructed its sales representatives to ask pharmacists to switch patients from Ambien to Ambien CR without seeking authorization from the prescribing physician and, in so doing, sought to induce the pharmacists to violate Cal. Bu. & Prof. Code Section 4052 et. seq. and the licensing regulations of other Plaintiff States as well.

83. Defendant engaged in these efforts contrary to law and its own "U.S. Code of Business Conduct, A Prescription for Compliance," in which Defendant specifically cited the Anti-Kickback Statute and stated that the statute "prohibits providing anything of value to a person with the intent to influence that person to recommend or purchase a health care product …that may be reimbursed by federal healthcare programs, including Medicare and Medicaid."

84. Moreover, Defendant's own U.S. Code of Business Conduct specifically addressed the exact situations that Relator Hamilton faced with doctors requesting to become "Speakers" in order to prescribe Ambien CR.

85. The U.S. Code of Business Conduct states in a Question and Answer section:

> Q: I am a sales professional and had a meeting with a physician last week who informed me that he would begin to increase the frequency with which he prescribes our product to his patients but only if we contracted him (and paid him) to speak at several upcoming conferences. I know that the Company contracts with physicians to provide a variety of services, so can we arrange to enter into a contract with this doctor?
>
> A: No. While sanofi-aventis does, on occasion, enter into arrangements with physicians to provide certain services (including speaking services), it is because there is a reasonable and unmet need for the services. Hiring a physician must never be based on the intent to influence prescribing practices or formulary decisions; otherwise, legitimate needs for these services may be tainted. Because one purpose of considering whether to enter into a speaking arrangement with this physician was based upon a desire to have this physician increase his prescribing of our products, the physician may not be retained.

86. However, when Dr. Sandeep Kapoor required that he become a speaker in order to prescribe Ambien CR, Defendant not only added Dr. Kapoor as a speaker, regardless of whether he was a competent speaker, but also supplied him with expensive dinners and hundreds of samples, acting exactly contrary to the Anti-Kickback statute as clearly described in its own U.S. Code of Business Conduct. Dr. Kapoor had also threatened to begin writing prescriptions for Lunesta and to become a speaker for Lunesta. Sanofi US Corporate Office rewarded these threats not only by making Dr. Kapoor part of the Speaker Program but also flying him to New York for training on Ambien CR and then also flying him to Paris for a clinical trial meeting. Relator also tried in vain to get other high prescribers such as Dr. Bass and Dr. Kupisk into the Speaker Program as a reward for their high volume of prescriptions but failed due to the extremely high competition to get doctors approved for the Speaker Program.

87. Moreover, Defendant was required to comply with California law by reporting meals and payments to physicians on a California Compliance website. In some cases, Relator Hamilton was told specifically to "forget" to include expensive meals on the list submitted on the California Compliance form. Where expensive dinners were reported on the California

Compliance site, sales representatives were told to increase the number of participants to fall under the per physician limits. As shown on multiple California Compliance submissions, the number of participants shown exceeds the actual number of participants.

F. Sanofi Disguised Kickback Payments to Doctors Through Continuing Medical Education Programs Such As Speaker Training and Speaker Programs

88. Sanofi also utilized so-called "Speaker Programs" as another way of disguising kickback money paid to induce the prescribing of Ambien and Ambien CR and to induce doctors to switch their patients from Ambien to Ambien CR. Admission into the Ambien Speakers Program was highly sought after by doctors because the program would pay doctors up to $100,000 a year. The marketing department controlled the highly competitive selection process which was based on only one criterion: how many Ambien and Ambien CR prescriptions the candidate doctor wrote. The program was conceived of and used as a reward for high prescribers.

89. Once selected as a Speaker, the doctor would be flown to expensive hotels and destinations to be trained by the Sanofi Marketing staff and subsequently, to deliver talks on Ambien and Ambien CR. Most of the time these trainings included off-label marketing messages that were prepared by the marketing department and sales representative for the doctor's use. The doctors were then paid between $1500 and $2000 per speaking event they attended. In some cases, the doctors who came to the events were also paid $300 just to passively listen and enjoy lavish meals, costing in the thousands of dollars.

90. The Speaker Program kickbacks were an integral part of Sanofi's efforts to switch Ambien patients to Ambien CR. Indeed, the day Ambien CR was approved by the FDA, Relator Hamilton's district sales manager sent out an email ordering all sales representatives to use

medical education funds to pay for speaker honorarium/fee to top-prescribing doctors.

91. Sales representatives were instructed to specifically seek to pay doctors who had high numbers of California Medicaid patients. One such doctor was Dr. Sandeep Kapoor who informed Sanofi that he would write prescriptions of Ambien CR if he was made a speaker and threatened to otherwise write Lunesta prescriptions. Dr. Kapoor also demanded an additional kickback in the form of 500 doses of flu vaccine during a period when the vaccine was in short supply. Although there were then no available slots in the Speaker Program, District Sales Manager Tim Miller made a special request to Sanofi Corporate Marketing to add Dr. Kapoor to the program and also provided his office with 500 doses of the flu vaccine. Relator Hamilton was instructed in writing to ask Dr. Kapoor to attend an Ambien dinner program and ask him at the same time if he would continue to write Ambien CR prescriptions. Dr. Kapoor later faced criminal charges relating to the death of actress Anna Nicole Smith.

92. Routinely, however, Speaker Programs were simply opportunities to treat doctors to expensive dinners where they would listen to a paid Sanofi speaker for a few minutes.

93. In some instances, expensive dinners were explicitly demanded by doctors before changing their prescription habits. In the case of the office of Drs. Trabulus, Kivowitz, Fishman, Delafield, and Goodman, the doctors required that Relator Hamilton and his sales representative partner treat them to at least two lavish dinners – in addition to the multiple office lunches they already received – before they would begin prescribing Ambien CR. One of these dinners costing over $3000 was held at the Matsuhisa restaurant in Beverly Hills on October 10, 2005.

G. Other Kickback Payments to Doctors Were Disguised Through the Use of All-Expense Paid International Trips to Sanofi Created Conferences

94. From 2003 through 2009, Defendant improperly paid physicians and other medical experts and researchers in the sleep field to promote on-label and off-label uses of

Ambien and/or Ambien CR.

95. From 2003 through 2009, Defendant organized and hosted a number of annual, international conferences in an effort to gather and influence one hundred top sleep experts, key opinion leaders, and researchers and promote on-label and off-label uses of Ambien and/or Ambien CR. Many of these physicians were U.S. physicians.

96. Each conference, titled International Sleep Disorder Forum was funded by Defendant's Global Group in Paris and was organized by Defendant's Global Marketing Department. This was a very large, extensive program and one of Defendant's biggest sales initiatives for its sleep franchise with a yearly budget of over $1 million, and planning that commenced one year in advance.

97. The purpose of each conference was for Defendant to "own" the thought leaders in sleep and to "get them in [Defendant's] camp."

98. Defendant sought to "own" leaders in the field of sleep health so that they would more easily be advocates or spokespeople for Ambien and/or Ambien CR and other sleep compounds under development.

99. Defendant improperly reimbursed and/or directly paid for the following types of expenses for an average of 100 Key Opinion Leader attendees per year:

a. Business-class round-trip international and/or domestic airfare to the destination;
b. Accommodations at 5-star hotels/resorts;
c. Ground transportation;
d. Meals and alcohol;
e. Other entertainment;
f. Honoraria;
g. Interaction with Sanofi Senior Corporate Leadership.

100. The average total cost paid by Sanofi for an attendee for one conference was $4,500 or more, excluding honoraria. Speakers received an average of at least $3,000 cash from

Sanofi in addition to all their expenses paid.

101. From 2003 through 2009, Defendant improperly paid over $5 million in kickbacks in the form of travel-related and other expenses for hundreds of conference attendees.

102. At each conference, attendees were furnished with, inter alia, CDs containing medical and scientific literature geared toward the off-label promotion and use of Ambien and/or Ambien CR. For example, the theme of the 2006 conference was focused on co-morbid issues and Defendant promoted the use of Ambien and/or Ambien CR for the treatment of conditions like GAD (Generalized Anxiety Disorder) and MDD (Major Depressive Disorder).

103. Indeed, Defendant conducted clinical trials to establish Ambien's and/or Ambien CR's efficacy in treating GAD and MDD, but their research did not support these conclusions.

104. Eventually, Defendant's U.S. - based legal and regulatory personnel began to question the propriety of the conference budget and expenses and sought to discern the business rationale for these lavish international conferences.

105. Defendant fraudulently prepared "rationale documents" stating that the purpose of these conferences was "scientific exchange" when, in reality the goal was to "wine and dine" sleep health experts so that they would promote the on-label and off-label use of Ambien and/or Ambien CR, and otherwise position Defendant and its other pharmaceutical products more favorably vis-à-vis its competitors.

106. The following Sanofi executives attended one or more of the International Sleep Disorder Forums held each year from 2003 to 2009:

a. John Lopos – Head of U.S. Interface to Global Marketing; Director of Marketing, CNS Franchise;
b. Adam Winseck – Director of Medical Affairs;
c. Charles Lay – Vice President of Marketing;
d. Isabelle Chone – Director of Marketing (Global Marketing – Paris);
e. Phillipe Emment – Medical Director (Global Medical Affairs – Paris);

f. Christopher Cala – Marketing Manager (Global Marketing – Paris).

107. The 1st International Sleep Disorders Forum was held in Montreal, Canada from October 3 to October 4, 2003. The theme for the 2003 forum was "The Art of Good Sleep," with approximately 100 attendees.

108. The 4th International Sleep Disorders Forum was held in Rome, Italy from September 7 to September 8, 2006. The theme for the 2006 forum was "Sleep and Comorbid Disorders," with approximately 100 attendees.

109. The 5th International Sleep Disorders Forum was held in Chicago, Illinois from September 27 to September 28, 2007. The theme for the 2007 forum was "Novel Outcome Measures of Sleep, Sleep Loss, and Insomnia," with approximately 100 attendees.

110. The 7th International Sleep Disorders Forum was held in Cannes, France from September 24 to September 25, 2009. The theme for the 2009 forum was "Sleep: homeostatic mechanisms and implications for its disorders," with approximately 100 attendees.

111. By organizing and hosting these conferences and inviting and paying for the attendance of hundreds of doctors, researchers, and other medical experts, Defendant provided unlawful kickbacks for the prescribing of Ambien, Ambien CR and the switching of patients from Ambien to Ambien CR. Sanofi also paid to publish the proceedings of this meeting in supplements of major sleep journals. They also developed their own journal called INSOM which Sanofi representatives distributed to other medical practitioners after the meeting.

H. Sanofi S.A. Achieved Enormous Sales of Ambien and Ambien CR Through Illegal Off-Label Marketing, Misbranding and False Claims of Superiority

112. In the very first year that Sanofi took over the marketing of Ambien, Sanofi roughly doubled the sales for Ambien through a strategy of illegal techniques, including kickbacks, off-label marketing, misbranding, best price violations and false claims of superiority.

Sanofi continued to use and refine this arsenal of illegal techniques through the introduction of Ambien CR and into the present day.

113. Off-Label Marketing occurs whenever an FDA approved drug is marketed for a purpose not specified in its label as an approved indication. The FDA strictly regulates the manufacturing and sale of prescription drugs to comply with its mandate to safeguard our nation's prescription medicines. No drug company is permitted to circumvent the FDA's authority by advertising or otherwise seeking to induce the use of one of its products for a purpose the FDA did not approve. However, the FDA does not regulate the practice of medicine and will not interfere with a physician's treatment decisions regarding the doctor's patients. Thus, the FDA will not inquire nor seek to regulate a physician's decision to treat a patient with a prescription drug in a manner or dose not formally authorized by the FDA. But any effort by a drug company to induce the non-FDA approved use of a drug whether through marketing in the form of advertising or verbal persuasion via its sales representatives is strictly prohibited.

114. Misbranding occurs whenever an FDA-approved drug is marketed in a way not supported by its label. Misbranding a drug differs from marketing a drug for an off-label purpose in that misbranding materially misrepresents the qualities of the drug, inconsistent with or beyond what is on the drug's FDA-approved label for the approved purpose.

115. False claims of superiority consist of assertions made about a prescription drug in an effort to distinguish the drug from competitor drugs, including representations that a drug is more effective or has fewer or less serious side effects, when those assertions are not authorized nor affirmed by the FDA-approved label.

116. Sanofi utilized all of these illegal techniques – off-label marketing, misbranding and false superiority claims – in sham programs like Continuing Medical Education, Advisory

Boards, Speaker Programs, consisting of membership in Sanofi's Speaker Bureau, Speaker Training and Speaker Presentations at Educational Outreach events, breakfasts, lunches, dinners, Corporate Sales Trainings attended by physicians, International Conferences, as well as in sales, visual aids and verbal pitches used by its sales representatives.

117. Speaker Programs: Admittance into Sanofi's "Speaker Programs" meant being exposed to off-label marketing, misbranding and false superiority claims and training in how to spread these illegal marketing techniques nationally throughout hundreds of medical communities. Doctors admitted into these programs were paid handsomely at a rate of $1,500 to $2,000 for appearing at various events organized by sales representatives. As explained earlier, admission into the Ambien Speakers Program was highly sought after by doctors because the program would pay doctors up to $100,000 a year. The marketing department controlled the highly competitive selection process which was based on only one criterion: how many Ambien and Ambien CR prescriptions the candidate doctor wrote. The program was conceived of and used as a reward for high prescribers and also used to spread Sanofi's illegal marketing techniques across the country as the trained speakers attended events where they might speak such as breakfast, lunch and dinner programs. Topics, slides and other visual aids and speaking points were all put together by the marketing department for the promotional speaker programs.

118. Continuing Medical Education ("CME"): Ostensibly designed to provide physicians and healthcare practitioners with continuing medical education credits, these CME programs were to be walled off from the Sanofi's marketing staff. In reality, Sanofi's CME division regularly consulted with brand managers to ask what off-label messages, misbranding and false superiority claims should be featured in the CME educational materials.

119. International Conferences: Invitations to the annual international conferences

hosted by Sanofi's Global Group in Paris and organized by Sanofi's Global Marketing department from 2003 – 2009, included round-trip business class airfare, all meals and accommodations, honorariums in the thousands of dollars and extensive exposure to off-label marketing, misbranding and false claims of superiority for both Ambien and Ambien CR. Conference attendees were furnished with, inter alia, CDs containing medical and scientific literature geared toward the off-label promotion and use of Ambien and/or Ambien CR. The 2006 Conference theme, for example, focused on the use of Ambien and/or Ambien CR for the treatment of Generalized Anxiety Disorder (GAD) and Major Depressive Disorder) (MDD) when such conditions occurred in "comorbidity" with insomnia. For this meeting, conference attendees who were Key Opinion Leaders (KOLs) in the sleep field were told that insomnia is a precursor to depression and vice versa, so treating the insomnia with a sleep aid such as Ambien CR would prevent or delay the onset of depression. Likewise, at that same 2006 conference, KOLs were told that insomnia was a precursor to GAD and vice versa, and were told that treating GAD with a sleep aid such as Ambien CR would prevent or delay the onset of GAD. Sanofi saw this as a very effective way to spread their illegal off-label promotion since after the conferences were over these KOLs would disseminate Sanofi's message to thousands of other healthcare practitioners.

120. Corporate Sales Training for Doctors: In some instances Sanofi found it more effective to fly physicians to their corporate sales training programs where the doctors were trained alongside sales representatives and subjected to intensive off-label marketing, misbranding and false superiority promotion. For example, Dr. Milton Erman was paid and flown to Orlando Florida during the launch of Ambien CR. There, Dr. Erman who was considered a KOL, helped the marketing team train the sales representatives who were present at

the launch meeting on how best to position Ambien CR to other physicians. Dr. Erman, using a slide deck developed by Sanofi's marketing department, told the sales representatives that an ideal sleep aid is one that gets into the body, builds up at night (enough to keep the patient asleep in the middle of the night), and rapidly leaves the blood stream before a patient awakens. He then told them that this ideal hypnotic does not exist and that is why Sanofi came up with an extended release form of Ambien (Ambien CR) to do what this ideal hypnotic could do. Dr. Erman made this superiority claim at the launch of Ambien CR in the presence of thousands of sales representatives. These same marketing slides with this superiority claim were used in speaker programs to doctors.

121. Sales Visual Aids & Leave Behinds: Sales visual aids in the form of power point slides, brochures, and ads all consistently promoted off-label purposes, misbranding and false claims of superiority. As with the 2006 International Conference theme, Sanofi's corporate sales department extensively off-label marketed Ambien and Ambien CR for conditions ranging from schizophrenia, depressive disorders, anxiety disorders, cardiovascular events, and use for post-menopausal women merely by inserting whichever condition they wished to target after the phrase "comorbid" as well as in blatantly unsupported assertions about insomnia being a precursor to psychiatric conditions like schizophrenia and dementia.

122. In materials "left behind" by sales representatives, false claims of superiority were set forth in charts comparing Ambien and generic Ambien with Ambien CR. Such "leave behinds" even included digital audio messages like the one in which Dr. Thomas Roth – Division Head Sleep Disorders and Research Center, Henry Ford Hospital – asserted the superiority of Ambien CR to generic Ambien (zolpidem tartrate 10 mg).

I. The FDA Approved Ambien for the Short-Term Treatment of Insomnia and Ambien CR for the Treatment of Insomnia Characterized by Difficulties With Falling Asleep and Staying Asleep – All Other Uses Are Off-Label

123. Ambien - zolpidem tartrate – was approved in 1992 by the FDA for the following indication, warnings and precautions:

> **DESCRIPTION**
> Ambien (zolpidem tartrate), is a non-benzodiazepine hypnotic of the imidazopyridine class and is available in 5-mg and 10-mg strength tablets for oral administration.
>
> **INDICATIONS AND USAGE**
> Ambien (zolpidem tartrate) is indicated for the short-term treatment of insomnia. Ambien has been shown to decrease sleep latency and increase the duration of sleep for up to 35 days in controlled clinical studies.
>
> **WARNINGS**
> Since sleep disturbances may be the presenting manifestation of physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after careful evaluation of the patient.
>
> **PRECAUTIONS**
> **Use in Patients with Concomitant Illness**: Clinical experience with Ambien (zolpidem tartrate) in patients with concomitant systemic illness is limited....
>
> **Use in depression**: As with other sedative/hypnotic drugs, Ambien should be administered with caution to patients exhibiting signs or symptoms of depression. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional overdose is more common in this groups of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.
>
> **DOSAGE AND ADMINISTRATION**
> The dosage of Ambien should be individualized.
> The recommended dose for adults is 10mg immediately before bedtime.
>
> The total Ambien dose should not exceed 10mg.

124. Ambien CR was approved by the FDA in 2005 for the following indication, warnings and precautions:

> **DESCRIPTION**
> Ambien CR contains zolpidem tartrate, a non-benzodiazepine hypnotic of the

imidazopyridine class. Ambien CR (zolpidem tartrate extended-release tablets) is available in 6.25 mg and 12.5-mg strength tablets for oral administration.

INDICATIONS AND USAGE
Ambien CR (zolpidem tartrate extended-release tablets) is indicated for treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance (as measured by wake time after sleep onset). *See Clinical Pharmacology Controlled trials supporting safety and efficacy.*)

The clinical trials performed in support of efficacy were both 3 weeks in duration, although the final formal assessments of sleep latency and maintenance were performed after 2 weeks of treatment.

WARNINGS
Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness which should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including zolpridem. Because some of the important adverse effects of zolpidem appear to be dose related (see *Precautions and Dosage and Administration*), it is important to use the smallest possible effective dose, especially in the elderly.

PRECAUTIONS
Use in Patients with Concomitant Illness: Clinical experience with Ambien (zolpidem tartrate) in patients with concomitant systemic illness is limited.

Use in depression: Sedative/hypnotic drugs should be administered with caution to patients exhibiting signs or symptoms of depression. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional overdose is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Information for patients: Patient information is printed at the end of this insert. To assure safe and effective use of Ambien CR, this information and instructions provided to the patient should be discussed with patients.

DOSAGE AND ADMINISTRATION
The dosage of Ambien should be individualized.

Ambien CR is available as extended-release tablets containing 6.25 mg or 12.5 mg of soppidem tartrate for oral administration. Ambien CR extended-release tablets should be swallowed whole, and not be divided, crushed, or chewed. The

effect of Ambien CR may be followed by ingestion with or immediately after a meal.

The recommended dose for adults if 12.5 mg immediately before bedtime.

125. In 2007, the following warning was added to the Ambien CR label:

WARNINGS
Because sleep disturbances may be the presenting manifestation of a physical and/or psychotic disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. **The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.** Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypnotic drugs, including zolpidem. Because some of the important adverse effects of zolpidem appear to be dose related (see *Precautions* and *Dosage and Administration*), it is important to use the smallest possible effective dose, especially in the elderly.

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g. aggressiveness and extroversion that seemed out of character), similar to effects produced by alcohol and other CNS depressants. Visual and auditory hallucinations have been reported as well as behavioral changes such as bizarre behavior, agitation, and depersonalization. Complex behaviors such as "sleep-driving" (i.e. driving while not fully awake after ingesting a sedative-hypnotic, with amnesia for the event) have been reported. These events can occur in sedative-hypnotic-naïve as well as in sedative-hypnotic-experienced persons. Although behaviors such as sleep driving may occur with zopidem alone at therapeutic doses, the use of alcohol and other CNS depressants with zolpidem appears to increase the risk of such behaviors, as does the use of zolpidem at doses exceeding the maximum recommended dose. Due to the risk to the patient and the community, discontinuation of zolpidem should be strongly considered for patients who report a "sleep-driving" episode. Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with sleep-driving, patients usually do not remember these events.

Amnesia, anxiety and other neuro-psychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking has been reported in association with the use of sedative/hypnotics.

It can rarely be determined with certainty whether a particular instance of the

abnormal behaviors listed above is drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

Following the rapid dose decrease or abrupt discontinuation of sedative/hypnotics, there have been reports of signs and symptoms similar to those associated with withdrawal from other CNS-depressant drugs (see *Drug Abuse* and *Dependence*)

Zolpidem, like other sedative/hypnotic drugs, has CNS-depressant effects. Due to the rapid onset of action, Ambien CR should only be ingested immediately prior to going to bed. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination such as operating machinery or driving a motor vehicle after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of Ambien CR. Zolpidem showed addictive effects when combined with alcohol and should not be taken with alcohol. Patients should also be cautioned about possible combined effects with other CNS-depressant drugs. Dosage adjustments may be necessary when Ambien CR is administered with such agents because of the potentially addictive effects.

PRECAUTIONS

"Sleep-Driving" and other complex behaviors: There have been reports of people getting out of bed after taking a sedative hypnotic and driving their cars, while not fully awake, often with no memory of the event. If a patient experiences such an episode, it should be reported to his or her doctor immediately, since "sleep-driving" can be dangerous. This behavior is more likely to occur when Ambien CR is taken with alcohol or other central nervous system depressants (see *Warnings*). Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with sleep-driving, patients usually do not remember these events.

INFORMATION FOR PATIENTS TAKING AMBIEN CR

Your doctor has prescribed Ambien CR to help you sleep. The following information is intended to guide you in the safe use of this medicine. It is not meant to take the place of your doctor's instructions. If you have any questions about Ambien CR tablets be sure to ask your doctor or pharmacist.

Ambien CR is used to treat different types of sleep problems, such as:

- Trouble falling asleep
- Waking up often during the night

Some people may have more than one of these problems.

Ambien CR belongs to a group of medicines known as the "sedative/hypnotics", or simply, sleep medicines. There are many different sleep medicines available to

help people sleep better. Sleep problems are usually temporary, requiring treatment for only a short time, usually 1 to 2 days up to 1 to 2 weeks. Some people have chronic sleep problems that may require more prolonged use of sleep medicine. However, you should not use these medicines for long periods without talking to your doctor about the risks and benefits of prolonged use.

SIDE EFFECTS
Most common side effects:

- headache
- somnolence (sleepiness)
- dizziness

You may find that these medicines make you sleep during the day. How drowsy you feel depends upon how your body reacts to the medicine, which sleep medicine you are taking, and how large a dose your doctor has prescribed. Daytime drowsiness is best avoided by taking the lowest dose possible that will still help you sleep at night. Your doctor will work with you to find the dose of Ambien CR that is best for you.

To manage these side effects while you are taking this medicine:

- when you first start taking Ambien CR or any other sleep medicine until you know whether the medicine will still have some carryover effect in you the next day, use extreme care while doing anything that requires complete alertness, such as driving a car, operating machinery, or piloting an aircraft.
- NEVER drink alcohol while you are being treated with Ambien CR or any sleep medicine. Alcohol can increase the side effects of Ambien CR or any other sleep medicine.
- Do not take any other medicines without asking your doctor first. This includes medicines you can buy without a prescription. Some medicines can cause drowsiness and are best avoided while taking Ambien CR.
- Always take the exact dose of Ambien CR prescribed by your doctor. Never change your dose without talking to your doctor first.

126. There are no other FDA-approved uses for either Ambien or Ambien CR.

J. Sanofi Failed to Give the Government the Required "Best Price" for Ambien CR by Paying Higher Rebates to Managed Care Companies than to the United States

127. Federal law requires that the United States receives the best price for prescription drugs as compared to private companies. The price given to Medicaid includes a mandated rebate discount of 15%. Sanofi regularly violated this requirement by giving rebates well in

excess of 15% to private managed care companies as an incentive to adding Ambien CR to their formularies. Companies such as Express Scripts Inc. (ESI) – a company that managed pharmacy benefits – and Blue Cross Blue Shields of Alabama (BCBS AL) were given discount rebates paid quarterly based upon utilization. At both ESI and BCBS AL the discount rebates amounted to 40%. Upon information and belief, Sanofi currently regularly violates the "Best Price" requirement.

K. Sanofi Also Violated the "Best Price" Requirement by Essentially Repackaging Ambien as Ambien CR and Charging a Higher Price for Ambien CR

128. As set forth in the complaint, there is no real scientific and medical difference between Ambien and Ambien CR. With the loss of Ambien's patent status, however, there did exist a significant price difference between them. Thus by marketing and selling Ambien CR to the United States, when the less expensive product Ambien would have achieved the same results, Sanofi caused the United States to pay more than it needed to pay for the sole purpose of adding to Sanofi's profits.

L. Sanofi Illegally Promoted Ambien and Ambien CR for Off-Label Uses Including But Not Limited to Preventive Treatment of Schizophrenia and Dementia; Prophylaxis Use With Depressed Patients and Patients Commencing SSRI-Drugs; Numerous Non-Insomnia Conditions; and, Dosages Higher than those Specified in the Label

129. Sanofi's off-label promotion of Ambien and Ambien CR began at least as early as 2001 and continues to the present day and encompasses an enormous range of conditions for which neither Ambien nor Ambien CR is indicated. Among the off-label uses and misbranding for which Sanofi promoted Ambien and Ambien CR were a variety of psychiatric disorders, including schizophrenia, depression, anxiety disorders, bipolar disorder, panic disorder; as well as pediatric disorders, Parkinson's disease, restless leg syndrome, jet lag, substance abuse,

including alcohol abuse, drug abuse, and withdrawal from both, Post Traumatic Stress Disorder, pre-op sedation, recovery from surgery; as a preventive measure against the onset of various psychiatric disorders, as a prophylaxis against insomnia brought on by the side-effect of other medications and/or any other non-insomnia condition, and, for use in high-dosages contrary to the label indication so that Sanofi could make more money than if physicians prescribed the lower dosage approved by the FDA.

130. Nor is the use of Ambien or Ambien CR for any of these off-label uses supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information. Sanofi has spent hundreds of millions of dollars on this aggressive and illegal off-label marketing campaign in the successful pursuit of sales in the billions of dollars.

1. Sanofi Promoted the Off-Label Use and Misbranding of Ambien and Ambien CR to Treat Psychiatric Patients

131. Sanofi aggressively sought to promote the use of Ambien and Ambien CR in treating patients suffering from psychiatric disorders. Corporate strategy explicitly directed the sales force to market the drugs to psychiatrists and a comprehensive set of misbranding and off-label claims were utilized consistently throughout face-to-face meetings, slide presentations given at conferences and speaker programs, as well as reliance upon unsupported and scientifically unsound studies and conclusions.

132. Marketing materials created by the marketing department and approved by Sanofi's corporate management as well as the legal-regulatory and continuing medical education departments consistently made medically unsupportable claims including, but not limited to, the assertion that Ambien and Ambien CR should be prescribed to prevent psychiatric disorders such as: Major Depressive Disorder; Mania; Bipolar; Schizophrenia; Dementia; Alzheimer's

Dementia; any Anxiety Disorder; Alcohol Abuse/Dependence ; Chronic Pain; and Seasonal Affect Disorder.

133. Neither Ambien nor Ambien CR was ever approved by the FDA for any use in the prevention of psychiatric disorders. Nor is there any support for such off-label use and/or misbranding in the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information. Indeed, both the FDA approved labels for Ambien and Ambien CR as well as Drugdex list strong warnings and precautions against the use of Ambien and Ambien CR with depressed patients. Potential dangers include worsening of depression and causing suicidal thinking.

134. In support of these off-label marketing efforts, Sanofi put forth faulty scientific claims, including assertions that insomnia is a recognized precursor to depression and seeking to falsely link insomnia to substance abuse like alcohol and drug abuse. These and numerous similarly scientifically baseless assertions were approved by the highest levels of Sanofi's corporate management and widely disseminated through marketing materials, sales representatives and at conferences and meetings.

2. Sanofi S.A. Also Promoted the Off-Label and Misbranded Use of Ambien and Ambien CR as a Prophylaxis to be Prescribed to Any Patient Taking Psychiatric Drugs Whether or Not the Patient Displayed Any Symptoms of Insomnia

135. Sales representatives like Relator Hamilton were directed to promote the use of Ambien and Ambien CR as a prophylaxis to be used with patients using or beginning to use psychiatric medications, including SSRI-medications. The sales representatives were to suggest an automatic 14-30 day course of Ambien and/or Ambien CR to be prescribed to all patients being put on psychiatric medication such as selective serotonin reuptake inhibitors (SSRIs). Supporting marketing materials for these efforts included charts showing the supposed negative

effects of various psychiatric medications and promoting the idea that administration of Ambien and/or Ambien CR would counter these effects.

136. Sanofi specifically targeted psychiatric practices – for example, Relator Hamilton was asked to develop an action plan for increasing the off-label use of Ambien for psychiatric patients. During face-to-face meetings with doctors, sales representatives like Relator Hamilton would circumvent the prohibition against distributing off-label marketing materials by having scientifically unsupported studies about off-label uses faxed to the doctor.

3. Sanofi S.A. Sought to Disguise Off-Label Marketing and Misbranding as Information About "Comorbid" Conditions

137. In an effort to disguise its off-label marketing and misbranding, Sanofi S.A. constantly used the word "comorbid" to connect Ambien and Ambien CR with a legion of other non-insomnia conditions and thereby misbrand the drugs for these off-label purposes.

138. For example, Ambien and Ambien CR were both promoted and advertised to treat insomnia when patients suffered "comorbid" anxiety or depression. In other words, Sanofi promoted Ambien and Ambien CR as being effective treatments for patients suffering from both insomnia and another condition such as depression or anxiety. However, in this example, neither anxiety nor depression were ever specifically analyzed with evidentiary support specified or sanctioned in the FDA-approved product label. The same was true for the host of other comorbid conditions promoted for Ambien and Ambien CR such as PTSD, mental health problems, and substance abuse to mention but a few. Nor does there exist any support for such treatment in the compendia, including DRUGDEX. Nor did Sanofi submit or gain approval for a new drug application for marketing to any subpopulation such as depressed patients or patients on SSRI drugs.

139. In practice, Sanofi's marketing department inserted whatever condition it chose

after the word "comorbid" in an effort to off-label market and misbrand Ambien and Ambien CR for conditions ranging from: psychiatric illness, arthritis, heart failure, pulmonary disorders, gastrointestinal disorders, Parkinson's disease, stroke and incontinence.

140. "Comorbid" off-label and misbranding arguments were disseminated through marketing materials presented at speaker training, speaker programs, international conferences, left with physicians and verbally pitched as part of the detailing done by sales representatives to physicians and pharmacists.

4. Sanofi S.A. Promoted an Off-Label High Dosage of Ambien In Order to Make Greater Profits

141. The FDA-approved dosage for Ambien was not to exceed 10 milligrams and for elderly patients the recommended dose was only 5 milligrams. Sanofi S.A., nevertheless, chose to promote double that dosage or 20 milligrams so as to increase profits. Sales representatives like Relator Hamilton were trained to regularly pitch the higher 20 milligram dose to doctors within his territory. This instruction occurred at all major training attended by Relator Hamilton throughout his employment with Sanofi. Written materials promoting the higher dose were also sent to physicians referencing a single study in which 20 milligrams were administered to 107 patients over a six-month period. Sales representatives and speakers were trained to represent this study as a finding that off-label higher doses of 20 milligrams were safe and tolerated well by patients.

M. Sanofi S.A. Misbranded Both Ambien and Ambien CR as Being An Effective Prophylaxis In Treatment of Underlying Mental Illnesses While Failing to Address Required Warnings in the Use of Ambien and Ambien CR With Depressed Patients and While Misrepresenting the Chemical Nature of Both Drugs

1. Misbranding Ambien and Ambien CR for Use as a Prophylaxis

142. Sanofi sought to promote the clinically criminal assertion that proactive treatment